

## Complete Summary

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### **GUIDELINE TITLE**

Primary care guidelines for the management of persons infected with human immunodeficiency virus: recommendations of the HIV Medicine Association of the Infectious Diseases Society of America.

### **BIBLIOGRAPHIC SOURCE(S)**

Aberg JA, Gallant JE, Anderson J, Oleske JM, Libman H, Currier JS, Stone VE, Kaplan JE. Primary care guidelines for the management of persons infected with human immunodeficiency virus: recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis 2004 Sep 1;39(5):609-29. [76 references] [PubMed](#)

### **GUIDELINE STATUS**

This is the current release of the guideline.

### **\*\* REGULATORY ALERT \*\***

### **FDA WARNING/REGULATORY ALERT**

**Note from the National Guideline Clearinghouse:** This guideline references a drug(s) for which important information has been released.

On September 20, 2005, the U.S. Food and Drug Administration announced on their Web site that the only U.S.-licensed manufacturer of varicella zoster immune globulin (VZIG) (Massachusetts Public Health Biologic Laboratories, Boston, MA) has discontinued manufacture of VZIG, which is indicated for patients in need of passive immunization to prevent severe varicella zoster infection.

On February 8, 2006, the FDA noted that the supply of the licensed VZIG product is nearly depleted. However, an investigational (not licensed) VZIG product (manufactured and currently under development by Cangene Corporation Winnipeg, Canada) is available under an investigational new drug application (IND) protocol. This product may be requested through FFF Enterprises (Temecula, CA) for individuals who have been exposed to varicella and who are at increased risk of complications from varicella. See the [FDA Web site](#) for more information.

In addition, the Centers for Disease Control and Prevention have released information regarding this new product (VariZIG™). See the [CDC Web site](#) for more information.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

## SCOPE

### DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Opportunistic infections and other diseases associated with HIV infection, including cytomegalovirus infection, hepatitis A, hepatitis B, hepatitis C, syphilis, gonorrhea, chlamydia infection, toxoplasmosis, and tuberculosis
- Metabolic complications of antiretroviral therapy

### GUIDELINE CATEGORY

Counseling  
Diagnosis  
Evaluation  
Management  
Screening  
Treatment

### CLINICAL SPECIALTY

Family Practice  
Infectious Diseases  
Internal Medicine  
Obstetrics and Gynecology  
Pediatrics  
Preventive Medicine

### INTENDED USERS

Advanced Practice Nurses  
Health Care Providers  
Nurses  
Physician Assistants  
Physicians

## **GUIDELINE OBJECTIVE(S)**

To assist health care providers in the primary care management of persons infected with human immunodeficiency virus (HIV), including a description of baseline laboratory screening and adherence issues

## **TARGET POPULATION**

- Human immunodeficiency virus (HIV)-infected persons and those at risk for infection, including infants and children of women infected with HIV (*screening and management*)
- All pregnant women (*screening*)
- Any individual requesting testing for HIV (*screening*)

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Diagnosis**

#### **Human Immunodeficiency Virus (HIV) Testing, Counseling, and Risk Screening**

1. Testing of all adults in populations with estimated prevalence of HIV infection greater than 1%; all pregnant women; those sexually assaulted; those with occupational exposure; those requesting testing for any reason
2. Serological testing for HIV antibodies (Oraquick; Unigold)
3. Confirmation of positive screening result by Western blot or immunofluorescence assay
4. Counseling of patients with risk behavior associated with HIV infection, those exhibiting signs or symptoms suggestive of HIV infection, those with tuberculosis or sexually transmitted diseases (STDs), HIV-seronegative persons regarding risk of HIV infection, and HIV-infected persons regarding nature of their infection and the risk of transmission
5. Risk screening for HIV-infected persons regarding high-risk behavior
6. Laboratory tests for STDs

### **Medical Management of Established HIV Infection**

#### **History and Physical Examination and Other Evaluations**

1. History and physical examination (history of present illness; past medical history; medication and allergies; social, sexual, and family histories and review of systems).
2. Laboratory studies including: serological testing for HIV; CD4 cell count; plasma HIV RNA load; HIV resistance testing; complete blood cell (CBC) count and chemistry panel; tuberculosis screening; glucose-6-phosphate dehydrogenase deficiency screening; serological testing for *Toxoplasma gondii*; viral hepatitis screening; screening for infections with cytomegalovirus (CMV) and other herpes-viruses; STD screening; serological testing for syphilis; testosterone levels; chest radiography; human papillomavirus (HPV) screening [liquid-based cytology]; other tests depending on the age and sex

- of the patient [urinalysis, electrocardiography, colonoscopy, mammography, or determination of thyroid-stimulating hormone])
3. Comprehensive gynecologic history including cervical cancer evaluation, pregnancy testing, discussion of childbearing goals, history of sexual and physical abuse, depression, and mammography for women with HIV infection.
  4. Screening pregnant women for syphilis and HBV, HCV, and group B streptococcal infections.
  5. Polymerase chain reaction (PCR) assay for HIV DNA for perinatally HIV-infected infants
  6. Staging of disease
  7. Establishing schedules of evaluations for care for adult and pediatric patients

#### *Monitoring*

1. Routine measurements of body weight and patient self-report of body shape changes
2. Fasting lipid glucose levels
3. Monitoring for lactic acidosis symptoms
4. Follow-up studies for those with baseline bone densitometry that shows osteopenia or osteoporosis or interventions with a bisphosphonate or other medical therapy

#### *Adherence*

1. Identification of specific method for measuring adherence to highly active antiretroviral therapy (HAART) in clinical practice (patient self-report, electronic medication monitoring devices, pill counts and pharmacy refill records)
2. HAART intervention strategies (patient-focused, regimen-focused, and provider-focused)

### **MAJOR OUTCOMES CONSIDERED**

- Morbidity and mortality due to human immunodeficiency virus (HIV) infection
- Risk of acquiring HIV infection
- Accuracy, sensitivity and specificity of diagnostic and screening tests
- Risk and incidence of HIV-associated complications
- Rate of transmission of HIV
- Rate of adherence to antiretroviral therapy

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
 Hand-searches of Published Literature (Secondary Sources)  
 Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Not stated

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

### **Quality of Evidence**

- I. Evidence from  $\geq 1$  properly randomized, controlled trial
- II. Evidence from  $\geq 1$  well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from  $>1$  center); from multiple time-series; or from dramatic results from uncontrolled experiments
- III. Evidence from opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committee

## **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not applicable

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Not stated

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **Strength of Recommendation**

- A. Good evidence to support a recommendation for use; should always be offered
- B. Moderate evidence to support a recommendation for use; should generally be offered
- C. Poor evidence to support a recommendation; optional
- D. Moderate evidence to support a recommendation against use; should generally not be offered
- E. Good evidence to support a recommendation against use; should never be offered

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Guidelines are reviewed by the Infectious Disease Society of America (IDSA) Practice Guidelines Committee for content and format. A final draft of the guideline is submitted to the Practice Guidelines Committee for approval. After approval is granted, the draft is forwarded to the IDSA Governing Council for final approval.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Levels of evidence (I-III) and grades of recommendation (A-E) ratings are defined at the end of the Major Recommendations field.

**Please note:** Guidelines endorsed by the United States Public Health Service, the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC), the Infectious Diseases Society of America (IDSA), or other accredited programs, provide supplemental information.

### Diagnosis of Human Immunodeficiency Virus (HIV) Infection

#### Testing and Counseling

HIV infection is typically diagnosed by means of serological tests that demonstrate the presence of antibodies to HIV. A positive screening test result by enzyme immunoassay (EIA) is confirmed by either Western blot or immunofluorescence assay. Rapid tests for HIV (Oraquick, OraSure Technologies; Unigold, Trinity Diagnostics), which are performed with whole-blood samples obtained by fingerstick, have recently been approved as screening tests by the US Food and Drug Administration (FDA); the Oraquick test has also been approved for plasma, serum, and oral fluid specimens. Specimens reactive in this test are termed "preliminary positive" and also require confirmatory testing.

Persons who should be offered counseling and testing include those reporting risk behaviors associated with human immunodeficiency virus (HIV) infection, those exhibiting signs or symptoms suggestive of HIV infection, and those with tuberculosis or sexually transmitted diseases (STDs) (see table 3 of the original guideline document). In populations with an estimated prevalence of HIV infection of >1% (e.g., hospitalized patients in inner cities), all adults should be offered testing. All pregnant women should be offered testing because of the availability of treatment to reduce the likelihood of mother-to-child transmission as well as maintenance of health of the mother. Testing should be offered to anyone who has been sexually assaulted. Those potentially exposed to HIV via an occupational exposure should follow the "Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis" (HBV, hepatitis B virus; HCV,

hepatitis C virus). Testing should also be offered to all persons requesting HIV testing for any reason.

HIV-seronegative persons should be counseled regarding risk of acquiring HIV infection. Because of the delayed appearance of HIV antibodies in persons recently infected, high-risk activity within the past 3 months should prompt repeated serological testing at 6, 12, and 24 weeks. Symptoms of acute retroviral syndrome (fever, lymphadenopathy, sore throat, malaise, and skin rash) in a person reporting recent high-risk behavior should prompt testing for plasma HIV RNA in addition to HIV antibody testing. It should be emphasized, however, that plasma HIV RNA testing is not approved for diagnostic purposes by the Food and Drug Administration (FDA); false-positive results have been reported and generally suggest low levels of viremia. A positive plasma HIV RNA test result should be confirmed by subsequent serological or virological testing.

HIV-infected persons should be counseled concerning the nature of their infection and the risk of transmission of HIV to others, in addition to being referred for various support services and for medical treatment (see Centers for Disease Control and Prevention [CDC's] counseling and testing guidelines for more information).

### **Risk Screening for HIV-Infected Patients**

#### **Screening**

Persistent high-risk behavior has implications for the health of the patient, as well as for the risk of transmission of HIV to others. Therefore, each visit of an HIV-infected person to a health care provider should include screening for high-risk behavior (**A-II**).

In addition, patients should be queried concerning symptoms of STDs at each visit (**A-I**). All patients should be screened with laboratory tests for STDs at the initial encounter (**A-II** for syphilis, for trichomoniasis in women, and for chlamydial infection in women aged less than 25 years; **B-II** for gonorrhea and chlamydial infection in all men and women), and thereafter, depending on reported high-risk behavior, the presence of other STDs, and the prevalence of STDs in the community (**B-III**) (see table 5 of the original guideline document).

Additional details concerning risk screening of HIV-infected persons can be found in the recommendations from CDC, Health Resources and Services Administration, National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America (IDSA).

#### **Behavioral Intervention**

General messages regarding risk reduction should be given at all health encounters, regardless of risk behaviors reported by the patient or perceived risk on the part of the health care provider. Such messages can be delivered by the provider, by others in the health care setting, or by educational materials (e.g., pamphlets, posters, videos) in the health care setting (**A-III**).

Tailored messages are critical for patients who report persistent high-risk behavior or who have symptoms or signs of STDs. In nearly all situations, the provider should offer brief counseling; in general, persons exhibiting risk behavior should also be referred to programs capable of offering more extensive intervention programs (**A-I**).

## **Medical Management of Established HIV Infection**

### **History and Physical Examination**

#### *History of Present Illness*

History of present illness should include the date of diagnosis of HIV infection and, whenever possible, the approximate date of infection. It is critical to take a thorough medication history for patients who have already received antiretroviral therapy. The medication history is generally more helpful than the results of resistance testing in estimating resistance that has developed during treatment with prior regimens. Such a history should include not only the drug combinations taken, but also response to each regimen, including virus load and CD4 cell count, drug toxicities, adherence, and prior resistance test results. Patients should be asked whether they can recall the lowest CD4 cell count they have ever had and the highest HIV load. Every effort should be made to obtain medical records from prior health care providers. Patients should be asked about prior HIV-associated complications, including opportunistic infections, malignancies, and HIV-related symptoms.

#### *Past Medical History*

Clinicians should ask about other medical conditions that might affect the choice of therapy or response to therapy, such as neuropathy, gastrointestinal disease, chronic viral hepatitis, hyperlipidemia, diabetes, or renal insufficiency. Other past medical conditions that have particular relevance for HIV-infected patients include prior chickenpox or shingles; tuberculosis or tuberculosis exposure, including results of tuberculin skin tests (TSTs); STDs; and gynecologic problems. It is important that the history also include questions about where the patient has lived and traveled. Patients should be asked about adult vaccinations, including dates of last tetanus booster, pneumococcal polysaccharide vaccine, and hepatitis A and B vaccination.

#### *Medications and Allergies*

Patients should be asked about the medications they take, including over-the-counter medications, medications taken infrequently, methadone, and dietary or herbal supplements. A discussion of allergies should include questions about hypersensitivity reactions to prior HIV therapies, including sulfonamides, nonnucleoside reverse-transcriptase inhibitors, and abacavir.

#### *Social, Sexual, and Family Histories*

The social history should include a discussion of the use of tobacco, alcohol, heroin, and recreational drugs, including marijuana, cocaine, and so-called "club



drugs," such as MDMA ("ecstasy") and ketamine, which may interact with some antiretroviral agents. Active injection drug users should be asked about their drug-using practices, the source of their needles, and whether they share needles. It is critical to take a careful sexual history in an open, nonjudgmental manner, asking about past and current sexual practices. Risk reduction counseling can be introduced during this discussion. Counseling should focus on reduction of risk both of HIV transmission to others and of "reinfection" and infection with other sexually transmitted pathogens to the patient. Patients should also be asked about their sex partners, sexual practices (including condom use and contraceptive use), and whether their partner(s) have been informed of the patient's HIV status. Patients should be encouraged to inform their partners of their HIV status. Laws vary from state to state regarding the obligation of health care providers to notify sex partners, and clinicians should be aware of such laws in their own jurisdiction. Patients should also be specifically asked whom they have informed of their HIV status, how they have been coping with the diagnosis of HIV infection, and what kinds of support they have been receiving. It is important to know about the patient's family, living situation, and work environment and how they have been affected by the diagnosis of HIV infection. Other pertinent information includes their housing issues, employment, and plans for having children. Family medical history, rarely relevant in the pre-HAART (highly active anti-retroviral therapy) era, has now become important as HIV-infected patients are living longer and are developing treatment-related hyperlipidemia and diabetes. Patients should be asked whether there is a history of myocardial infarction in a first-degree relative before the age of 55 years for male relatives and the age of 65 years for women.

### *Review of Systems*

The review of systems should be thorough and comprehensive and should include questioning about common HIV infection-related symptoms, including fever, night sweats, weight loss, headaches, visual changes, oral thrush or ulceration, swallowing difficulties, respiratory symptoms, diarrhea, skin rashes or lesions, and changes in neurological function or mental status. Patients should be questioned about how their current weight compares with what they consider their normal or baseline weight. Depression is common among HIV infected patients, and the review of systems should include questions focusing on changes in mood, libido, sleeping patterns, appetite, concentration, and memory.

### *Physical Examination*

A complete physical examination should be done for all patients at the initial encounter. Special attention should be paid to examination of the skin, looking for evidence of seborrheic dermatitis, Kaposi sarcoma, folliculitis, fungal infections, psoriasis, and prurigo nodularis. The overall body habitus should be assessed, especially for patients taking antiretroviral therapy, who may have drug-related lipodystrophy, with evidence of fat accumulation and/or lipoatrophy. Funduscopic examination should be done, and for patients with advanced HIV disease (CD4 cell count,  $< 50$  cells/mm<sup>3</sup>), it may be appropriate to refer the patient to an ophthalmologist for a slit-lamp examination while dilated to screen for cytomegalovirus (CMV) retinitis and other ocular manifestations of HIV infection. The oropharynx should be carefully examined, noting evidence of candidiasis, oral hairy leukoplakia, mucosal Kaposi sarcoma, aphthous ulceration, and periodontal

disease. It is important to perform a careful anogenital examination for evidence of STDs, including condylomata and herpes simplex lesions. Examination of HIV-infected women should include careful palpation of the breasts and pelvic examination. The pelvic examination should include visual inspection of the vulva and perineum for evidence of genital ulcers, warts, or other lesions. Papanicolaou (Pap) test should be obtained to rule out cervical dysplasia. The neurological examination should include a general assessment of cognitive function, as well as motor and sensory testing.

## **Baseline Evaluation: Diagnostic and Screening**

### *Serological Testing for HIV*

Patients who have no documentation of their HIV serological test results or who were tested anonymously should undergo an additional serological test for HIV (**A-III**). Seropositive patients who are asymptomatic and have normal CD4 cell counts and undetectable or very low virus loads should undergo repeated serological testing.

### *CD4 Cell Counts*

A CD4 cell count should be obtained and confirmed (**A-II**). The CD4 cell count is used to stage HIV disease, to help establish the risk of specific HIV-associated complications, to determine the need for prophylaxis against opportunistic infection, to determine the need for therapy, and to assess response to antiretroviral therapy. It is important that the clinician and patient be aware of the substantial variation in CD4 cell counts. CD4 cell counts may be affected by medications and intercurrent illnesses. It is best to obtain 2 CD4 cell counts at baseline at least 1 week apart. Although the absolute CD4 cell count is the number most often used in clinical practice, the CD4 cell percentage can also be used to assess immune function and is somewhat less variable than the absolute count. Total CD4 cell counts of 200 and 500 cells/mm<sup>3</sup> generally correspond to CD4+ cell percentages of 14% and 29%, respectively. The use of the ratio of CD4 cells to CD8 cells is no longer advocated (**C-III**).

### *Plasma HIV RNA Load*

A quantitative HIV RNA determination (virus load) should be obtained (**A-II**). Consideration should be given to obtaining 2 virus load determinations at baseline at least 1 week apart because of variability in test results and potential for intercurrent illnesses. The standard assay should be ordered in the initial evaluation of the untreated patient. The ultrasensitive assay should be reserved for patients whose virus loads are expected to be low.

### *HIV Resistance Testing*

Because drug-resistant virus can be transmitted from one person to another, patients presenting during or shortly after primary infection should be tested for transmitted drug resistance (**B-II**). A resistance test at this stage is likely to detect the resistance pattern of the infecting virus strain. The results of early resistance assays may be useful in guiding therapy, even if treatment is deferred

for many years (**B-III**). With time, however, resistant virus will be overgrown by wild-type virus, and resistance tests will be less sensitive in detecting acquired resistance. A baseline resistance test for a patient with chronic infection is helpful only if it yields positive results: the absence of resistance does not mean that the patient does not harbor drug-resistant virus. Resistance testing should be offered to antiretroviral-naïve subjects (those who have never taken any antiretroviral medications) who are initiating therapy and who have been infected for less than 2 years and perhaps longer. It is often difficult to ascertain how long a person has been infected, and consideration should be given to testing when the duration is uncertain and the expected regional prevalence of resistance is greater than 5% (**B-II**). Resistance testing should be done for patients experiencing virological failure to guide changes in antiretroviral therapy, and resistance testing should always be done during pregnancy (**A-II**).

#### *Complete Blood Cell (CBC) Count and Chemistry Panel*

A CBC count and chemistry panel should be obtained (**A-III**). Anemia, leukopenia, and thrombocytopenia are common in HIV-infected persons and are readily detected with a CBC count.

#### *Glucose-6-phosphate Dehydrogenase (G6PD)*

G6PD deficiency is a genetic condition that predisposes to hemolysis following exposure to oxidant drugs. Screening for G6PD deficiency is recommended either at baseline or before initiating therapy with an oxidant drug for patients with the susceptible racial or ethnic background (**B-III**).

#### *Tuberculosis Screening*

HIV-infected patients should be tested for *Mycobacterium tuberculosis* infection by tuberculin skin test (TST) applied on the volar surface of the forearm by the Mantoux (intradermal injection) method with an intermediate-strength purified protein derivative (PPD) (0.1 mL containing 5 tuberculin units [TU]) (**A-I**). For an HIV-infected person, an induration of  $\geq 5$  mm is considered a positive result and should prompt chest radiography and evaluation for possible tuberculosis. Annual testing should be considered for those who have negative results by TST but are at high risk for exposure to tuberculosis. Repeated testing should also be considered for those who had negative TST results but who have subsequently experienced an increase in the CD4 cell count due to antiretroviral therapy and thus may have restored sufficient immunocompetence to mount a positive reaction (**B-III**). A TST should be performed any time there is concern of a recent exposure. HIV-infected persons who are close contacts of persons with infectious tuberculosis should be treated for latent *M. tuberculosis* infection--regardless of their TST results, age, or prior courses of treatment--after the diagnosis of tuberculosis has been excluded (**A-II**). Routine anergy testing is no longer recommended because of the variability of reagents and its poor predictive value and because prophylaxis given to anergic persons has been shown to prevent few cases of tuberculosis. If someone was vaccinated with bacille Calmette-Guerin, he or she may have a positive TST result. This reaction may be due to the vaccine itself or to latent *M. tuberculosis* infection; therefore, further workup to exclude tuberculosis with consideration of therapy for latent infection is warranted.

### *Serological Testing for Toxoplasma gondii*

All HIV-infected patients should be tested for prior exposure to *T. gondii* by measuring anti-*Toxoplasma* IgG (**B-III**). *Toxoplasma*-seronegative adults, representing 70%-90% of the US population, should be counseled on how to avoid new infection, primarily through the proper preparation of meat and the appropriate handling of cat feces (**B-III**). Serological testing should be repeated for previously seronegative persons if the CD4 cell count decreases to 100 cells/mm<sup>3</sup> and if they are unable to take trimethoprim-sulfamethoxazole for prophylaxis against *Pneumocystis jirovecii* (formerly *carinii*) pneumonia (**C-III**). If *Toxoplasma* serological tests yield positive results, the patients should be managed according to the guidelines. Although serological tests for *Toxoplasma* can never be used to diagnose or exclude toxoplasmosis, a seronegative patient with a space-occupying lesion of the CNS is less likely to have toxoplasmosis than is a seropositive patient.

### *Viral Hepatitis Screening*

HIV-infected patients should be screened for evidence of prior HBV infection by determination of hepatitis B surface antigen (HBsAg), antibody to HBsAg (HBsAb), and, possibly, antibody to hepatitis B core antigen (HBcAb) (**A-III**), and those who remain susceptible should be vaccinated against HBV (**B-II**). Partners of persons who are positive for HBsAg should be offered vaccination. Patients who are negative for HBsAg and HBsAb but positive for HBcAb should be screened for chronic HBV infection by determination of HBV load (PCR for HBV DNA) (**C-III**). There are no data to support vaccination against HBV for persons who are positive for HBcAb only. HIV-infected persons should be screened for HCV infection with a test for HCV antibody (**B-III**). Positive test results should be confirmed by measurement of HCV RNA by PCR (**A-II**). HCV RNA should also be measured for HCV-negative persons with unexplained liver disease, because approximately 6% of HIV-positive persons do not develop HCV antibodies. Hepatitis A vaccine is safe for use in HIV-infected patients and should be considered for patients without prior exposure (negative for total antibody to hepatitis A virus) (**B-III**). Prevacination screening is cost-effective when there is a seroprevalence of hepatitis A virus of >30% in the population being screened. Hepatitis A vaccination should be administered to all nonimmune patients who are coinfectd with HCV because of the increased risk of fulminant hepatitis A in HCV-positive persons (**B-III**).

### *Screening for Infections with Cytomegalovirus (CMV) and Other Herpesviruses*

Patients at lower risk of CMV infection (i.e., populations other than men who have sex with men or injection drug users, who may be assumed to be CMV positive) should be tested for latent CMV infection by serological testing for anti-CMV IgG (**B-III**). Although seroprevalence of CMV among HIV-infected persons is high, the identification of seronegative patients allows for the use of CMV-negative or leukocyte-reduced blood products when transfusions are needed, thus reducing the risk of iatrogenic CMV infection. It may also be valuable to determine anti-varicella IgG for the minority of patients who are unable to give a history of chickenpox or shingles. Patients who are seronegative should receive postexposure prophylaxis with varicella zoster immune globulin as soon as possible after exposure to a person with chickenpox or shingles (**A-III**).

Serological testing for other herpesvirus infections is not usually recommended, because it has no diagnostic or therapeutic applications, although some experts do recommend type-specific testing for herpes simplex virus type 2 for both men and women.

### *STD Screening*

HIV-infected persons, who are asymptomatic for STDs, regardless of risk behavior, should be screened at the initial visit for syphilis (**A-II**) and for gonorrhea and chlamydial infection (**B-II**). Women should have a pelvic examination and should have a wet mount examined for *Trichomonas* species (**A-II**). A variety of screening tests for gonorrhea and chlamydial infection are available, including nucleic acid amplification tests, nucleic acid hybridization tests, and culture. Periodic follow-up screening should be considered depending on reported risk behavior, the presence of other STDs, and the prevalence of STDs in the community (**B-III**) (see table 5 of the original guideline document).

### *Serological Testing for Syphilis*

A nontreponemal test for syphilis, such as a rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL) test, should be done at baseline (**A-II**) and repeated periodically, depending on the patients risk behavior and presence of other STDs (**B-III**). Biologically false-positive test results are not uncommon and can be excluded with a confirmatory test (i.e., fluorescent treponemal antibody absorption test [FTA-ABS] or microhemagglutination test for antibodies to *T. pallidum* [MHA-TP]). False-positive results of RPR and VDRL tests are generally of low titer. Opinions vary on the need for lumbar puncture for HIV-infected patients with evidence of syphilis. Most authorities would recommend that a lumbar puncture be done for all HIV-infected patients with latent syphilis (>1 year's duration), or for patients with early syphilis (<1 year) when accompanied by neurological signs or symptoms or when standard therapy with benzathine penicillin cannot be used (**B-III**). Patients who experience a therapeutic failure should also undergo lumbar puncture (**B-III**). Unfortunately, the interpretation of cerebrospinal fluid (CSF) findings can be difficult, because the VDRL tests of CSF are insensitive and the mononuclear pleocytosis and elevated CSF protein level characteristic of neurosyphilis are also common manifestations of HIV infection.

### *Human Papillomavirus (HPV) Screening*

Women should have a Pap test at the initial evaluation (**A-I**). Liquid-based cytology is the preferred approach for HPV testing.

Anal cytological screening of HIV-infected men who have sex with men has not yet become standard of care but is now being done for high-risk persons in some health care centers and may become a useful preventive measure in the near future.

### *Fasting Lipid Profiles*

Because many antiretroviral agents cause increases in cholesterol and triglyceride levels, blood should be drawn at baseline from fasting HIV-infected patients for determination of lipid profiles, especially for patients who are about to start therapy (**B-III**). Follow-up testing and response to therapy should be in accordance with current National Cholesterol Education Program guidelines.

#### *Testosterone Levels*

HIV-infected men are at risk for hypogonadism, especially with more advanced disease. Whether antiretroviral therapy ameliorates or contributes to this condition is unclear. Clinicians should consider drawing blood in the morning for determination of serum total and free testosterone levels in patients who complain of fatigue, weight loss, loss of libido or erectile dysfunction, or depressive symptoms (**C-III**).

#### *Chest Radiography*

HIV-infected patients are susceptible to a variety of pulmonary complications and infections. A baseline chest radiograph may be useful, in part for detection of asymptomatic tuberculosis (**B-III**).

#### *Other Laboratory Tests*

Other tests that may be indicated, depending on the age and sex of the patient, include urinalysis, electrocardiography, determination of thyroid-stimulating hormone, colonoscopy, or mammography. Routine testing for cryptococcal infection by determination of serum cryptococcal antigen or for disseminated *Mycobacterium avium* complex infection by culture of blood for acid-fast bacilli is not recommended (**D-III**).

### **Special Considerations for Women**

As part of the initial assessment, a comprehensive gynecologic history should be obtained, including menstrual history; sexual practices; contraception history and current use; male or female condom use and consistency of use; previous sexually transmitted and other genital tract infections; prior abnormal Pap test results, including evaluation and treatment; history of gynecologic surgery or other illnesses (e.g., uterine fibroids, endometriosis, and infertility); and current gynecologic symptoms (e.g., abnormal vaginal discharge, abnormal vaginal bleeding or amenorrhea, and pelvic pain).

More in-depth discussion about childbearing early in the course of HIV care is indicated if the patient expresses desire for future pregnancy, she is not trying to conceive but is not using appropriate contraception, or she expresses uncertainty about reproductive plans. The goal is to ensure informed decisions about contraception and to offer preconception counseling if pregnancy is desired. Patients should explicitly be asked to communicate with their provider if their plans change, when they are ready to consider pregnancy, or when they have questions related to reproduction.

As part of the initial evaluation and at periodic intervals, providers should assess the presence of depression and domestic violence in women by means of direct questions or validated screening tools (**B-III**). A basic pregnancy history should also be included: number of pregnancies and outcomes (miscarriage, abortion, ectopic pregnancy, stillbirth, and preterm or term live birth), significant obstetrical complications, and number of living children and their HIV and general health status. Women who are HIV positive should be instructed not to breast-feed, given the risk of transmitting HIV to the infant.

### *Pregnancy Testing*

Because of issues related to perinatal HIV transmission, the potential impact of HIV and treatment on mother, fetus, and pregnancy course, and the life-threatening nature of ectopic pregnancy, health care providers should question female patients about interval menstrual history and sexual and contraceptive practices at each visit. Pregnancy testing should be considered in the following situations: missed menses (unless using levonorgestrel implants or depot medroxyprogesterone acetate), irregular bleeding (unless using levonorgestrel implants or depot medroxyprogesterone acetate), new onset of irregular bleeding after prolonged amenorrhea while using levonorgestrel implants or depot medroxyprogesterone acetate, new-onset pelvic pain, enlarged uterus or adnexal mass on examination, before institution of new therapies, or at the patient's request.

### *Gynecological Evaluation for Cervical Cancer Screening and Prevention*

Both the CDC and the Agency for Health Care Policy and Research recommend that HIV-infected women have a Pap test as part of their initial evaluation and that this should be repeated once within the first year after diagnosis (**A-I**). If the results are normal, annual Pap tests are indicated (**A-II**). More frequent Pap tests should be considered in the following circumstances: if there is a previous history of an abnormal Pap test, after treatment for cervical dysplasia, in women with symptomatic HIV infection, and in women with HPV infection. HIV-infected women, who have had a hysterectomy, particularly if they have had a history of abnormal cervical cytology before or at the time of the hysterectomy, are at increased risk for SIL on vaginal cytological testing and should undergo regular screening with Pap tests.

Pap test results should be reported according to the Bethesda System. The results should include a statement on specimen adequacy and general categorization (negative for intraepithelial lesion or malignancy, epithelial cell abnormality, or other). Specimens that are reported as unsatisfactory for evaluation should be repeated. The presence of epithelial cell abnormalities (atypical squamous cells [ASC], SIL, glandular cell abnormalities, and squamous cell carcinoma) requires further evaluation. Women with ASC (both ASC-US [ASCs of unknown significance] and ASC-H [ASCs cannot rule out high-grade squamous intraepithelial lesion]), atypical glandular cells, SIL (low-grade or high-grade), or squamous carcinoma noted by Pap testing should undergo colposcopy and directed biopsy (**A-II**).

### *Mammography*

At present, breast screening by mammography for women with HIV infection should follow standard guidelines. Mammography should be performed every 1-2 years for women 40-50 years of age and annually after the age of 50 years (**A-I**). Mammography should be done before the age of 40 years for women with a history of breast cancer, with a first-degree relative or multiple other relatives with a history of premenopausal breast cancer or breast and ovarian cancer, or with a persistent palpable mass or other suspicious finding on examination.

### **Special Considerations for Children >13 Years Old**

Perinatal HIV infection is for the most part a preventable disease if pregnant women receive antiretroviral therapy as outlined in the "Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States." In the United States, the diagnosis of perinatal HIV infection is typically made within the first 6 months of age through routine screening of children born to known HIV-infected mothers.

Diagnosis of active HIV infection in the infant can be differentiated from HIV exposure by a PCR assay for HIV DNA. When 2 PCR assays are performed 1 month apart, with 1 assay after 4 months of age, the sensitivity and specificity is >98%. Once the diagnosis of perinatal HIV infection is made by detection of HIV DNA by PCR, HIV RNA PCR assays are subsequently used to monitor virus load. Perinatally HIV-infected infants have higher virus loads than do adults, reflecting primary infection, but as in adults, the virus load response to antiretroviral therapy is a strong predictor of prognosis.

There are also age-specific differences in CD4 cell counts, with infants having higher absolute counts than adults. From birth through 12 months of age, the normal CD4 cell count is >1500 cells/mm<sup>3</sup>; between 2 and 5 years, it is >1000 cells/mm<sup>3</sup>; only after 6 years of age do normal CD4 cell counts compare with adult counts of >500 cells/mm<sup>3</sup>. The percentage of CD4 cells that define as normal, moderate, or severe immunosuppression is the same for infants and children as for adults. Periodic monitoring of CD4 cell counts is an important predictor of treatment response and prognosis.

In addition to HIV infection, clinicians should screen pregnant women for other infections, including syphilis and HBV, HCV, and group B streptococcal infections, to determine whether to evaluate and/or treat the newborn. In the United States, there is a single FDA-approved rapid HIV test, with others soon to be available. These rapid tests are useful for women who present in labor without having been tested during the prenatal period, so that antiretroviral therapy can be administered to the mother and infant. Increasingly, infants are born to antiretroviral-experienced mothers who may have received multiple combination regimens, including all major classes of antiretroviral drugs. Unfortunately for HIV-infected children born to these mothers, there are no data to guide selection of newborn antiretroviral drug treatment regimens on the basis of maternal HIV resistance testing. Although it may be prudent to take resistance of maternal virus into consideration, present pediatric antiretroviral treatment guidelines do not address this issue.

### **Staging of Disease**



## *Adults*

The most widely used system for staging HIV disease is the 1993 revision of the CDC's AIDS Surveillance Case Definition for Adolescents and Adults. HIV disease is a continuous spectrum. These stages are used for determining resources, especially those from governmental sources, research, epidemiology and prognosis. According to this system, individuals are assigned a stage according to a 3 X 3 matrix consisting of 3 CD4 cell count categories and 3 clinical categories (see table 9 in the original guideline document).

CD4 cell count categories are as follows: category 1, CD4 cell count of  $\geq 500$  cells/mm<sup>3</sup> or  $\geq 29\%$ ; category 2, CD4 cell count of 200-499 cells/mm<sup>3</sup> or 14%-28%; category 3, CD4 cell count of  $< 200$  cells/mm<sup>3</sup> or  $< 14\%$ . Clinical categories are as follows: category A is documented HIV infection, asymptomatic, including persistent generalized lymphadenopathy, or acute HIV infection. Category B is symptomatic disease, with conditions not listed in clinical category C, including conditions that are attributed to HIV infection or indicative of a defect in cell-mediated immunity or considered to have a clinical course or management that is complicated by HIV infection. This includes conditions such as bacillary angiomatosis, persistent or recurrent thrush, poorly responsive vulvovaginal candidiasis, moderate to severe cervical dysplasia, constitutional symptoms (such as fever [temperature, 38.5 degrees C] or diarrhea of  $> 1$  months duration, oral hairy leukoplakia), herpes zoster ( $> 1$  episode or  $> 1$  dermatome), idiopathic thrombocytopenic purpura, listeriosis, pelvic inflammatory disease, and peripheral neuropathy. Category C is the AIDS indicator condition. Once a category C condition has occurred, the person remains in category C.

According to the 1993 case definition for AIDS, persons with stage A3, B3, C1, C2, or C3 infection have CDC-defined AIDS. Specifically, anyone with either an AIDS indicator condition or a CD4 cell count of  $< 200$  cells/mm<sup>3</sup> has AIDS. Once a diagnosis of AIDS has been made, for surveillance purposes, it is not negated by subsequent developments (e.g., persons given a diagnosis of AIDS on the basis of a CD4 cell count of  $< 200$  cells/mm<sup>3</sup> are still considered to have AIDS if their CD4 cell count subsequently increases to  $\geq 200$  cells/mm<sup>3</sup>, perhaps in response to antiretroviral therapy), even though the relevance of the diagnosis may then be more historical than clinical. Many states use the CDC classification as a criterion for accessing social services. Although reporting requirements for HIV infection vary from state to state, all cases of AIDS must be reported to the local health department. Accurate and complete reporting is important to ensure that adequate resources are available, because the amount of federal AIDS funding received by a city or community is frequently based on the number of reported cases from that region.

## *Children*

The CDC pediatric clinical and laboratory classification system parallels the adult HIV case definition. The major modification is the recognition that 3 age-related CD4 cell categories define levels of immunosuppression (see table 10 in the original guideline document).

There is no acute HIV syndrome recognized in pediatric patients as there is in adults. Infants and children are more likely to present with common bacterial

infections, chronic diarrhea with failure to thrive, or acute encephalopathy rather than the illnesses seen in adults defined in categories B or C.

## **Schedule of Evaluations for Care**

### *Adults*

The frequency of evaluation depends in part on the stage of HIV disease and in part on the rate at which disease is progressing. As a general rule, both the CD4 cell count and the virus load determine the frequency with which monitoring is needed. Asymptomatic patients with normal CD4 cell counts and low virus loads can be monitored infrequently, repeating virus load measurements every 3-4 months and CD4 cell counts every 3-6 months (**B-III**). CBC counts and chemistry panels should also be monitored to assess medication toxicity if the patient is given prophylaxis for opportunistic infections and/or antiretroviral therapy. Once therapy has been initiated, the response to therapy should be monitored 4-8 weeks later with a repeated virus load determination. Once the virus load has become undetectable, laboratory tests can then be obtained at 3-4-month intervals to monitor for drug toxicity and to assess response to therapy. The virus load and CD4 cell count should not be measured within 2-3 weeks of an illness or immunization. CD4 cell counts should be followed both for assessment of antiretroviral efficacy and to determine the need for prophylaxis against opportunistic infections (**A-II**). Pap tests should be repeated yearly (**A-II**). Screening tests for STDs and TSTs should be repeated periodically depending on behavioral risk and possible exposure to patients with tuberculosis (**B-III**). Testing for hepatitis should be repeated if suspected exposure occurs in a patient who was not previously immune. Patients who were previously seronegative for CMV should be retested if their CD4 cell count decreases to  $<50$  cells/mm<sup>3</sup>. Patients who have IgG to CMV detected should undergo funduscopy examinations by a qualified ophthalmologist once their CD4 cell count decreases to  $<50$  cells/mm<sup>3</sup>. Patients who were previously seronegative for *Toxoplasma* species should be retested if their CD4 cell count decreases to  $<100$  cells/mm<sup>3</sup> and if they are not receiving trimethoprim-sulfamethoxazole for prophylaxis against *P. jiroveci* pneumonia (**C-III**). Vaccinations for pneumococcal infection, influenza, and hepatitis should be offered as indicated.

### *Pediatric Patients*

HIV-exposed newborns should be observed closely for signs and symptoms of HIV infection, for comorbid conditions, and for confirmatory laboratory diagnosis. HIV-negative babies and children should have clinical visits as per standard of care. Vaccination against chickenpox should be given only to asymptomatic, nonimmunosuppressed children. Children with severe immunosuppression should not receive measles-mumps-rubella vaccine. All HIV-infected children should be vaccinated against pneumococcal disease and influenza. As with adults, appropriate use of combination antiretroviral drugs, with routine monitoring of adherence, immune status, virus load, and viral resistance, has become part of routine care for pediatric HIV patients.

## **Metabolic Complications of Antiretroviral Therapy**

### *Morphological or Body Shape Changes*

Routine measurements of body weight and patient self-report of body shape changes are sufficient for clinical practice. At the current time, there are no approved interventions for the treatment of fat accumulation and or lipoatrophy.

### *Lipid Abnormalities*

Fasting lipid levels should be monitored prior to and within 4-6 weeks after starting antiretroviral therapy (**B-III**). Patients with abnormal lipid levels should be managed according to the National Cholesterol Education Program guidelines, with special consideration, as discussed in the lipid guidelines, for persons with HIV infection.

### *Abnormalities of Glucose Metabolism*

Fasting glucose levels should be measured prior to and during antiretroviral therapy. At the current time, routine monitoring of insulin levels and/or oral glucose tolerance testing is not recommended (**C-III**). Weight loss and regular exercise should be recommended for obese patients. Switching from protease inhibitors to other agents may lead to resolution of hyperglycemia and diabetes, although this is not feasible for all patients. Whenever possible, treatment of protease inhibitor-induced diabetes should include the use of an insulin-sensitizing agent (metformin or thiazolidinediones), because the mechanism of hyperglycemia is insulin resistance.

### *Lactic Acidosis*

Patients starting NRTI therapy should be made aware of the symptoms of lactic acidemia and asked to report them promptly to their health care provider. A serum venous lactate level should be determined in the setting of unexplained but consistent symptoms. If abnormal, the measurement should be repeated, and arterial blood gas measurement should be considered. There is no rationale for ordering these laboratory studies for asymptomatic patients, either at the time of initiation of NRTI therapy or during the course of antiretroviral treatment (**E-II**). Discontinuation of NRTI drugs is recommended for symptomatic patients with a venous lactate level of >5 mmol/L (**B-II**).

### *Bone Disorders*

Patients taking antiretroviral therapy who have other risk factors for premature bone loss should consider undergoing bone densitometry at baseline (**B-III**). Calcium and vitamin D supplementation should be prescribed, and patients should be encouraged to exercise regularly and to not smoke cigarettes. If baseline bone densitometry shows osteopenia or osteoporosis, intervention with a bisphosphonate or other medical therapy should be considered. A follow-up study 1-2 years later to monitor the response to therapy is advised. Baseline bone densitometry is recommended for all women over the age of 65 years and for postmenopausal women under the age of 65 years who have 1 or more additional risk factor(s) for accelerated bone loss. Routine screening for osteoporosis in other HIV-infected patients cannot be recommended at this time (**D-III**). Patients should be reminded of the health benefits of regular exercise and adequate calcium and vitamin D intake. They should also be counseled regarding cigarette smoking and excessive alcohol consumption.

## **Adherence to Antiretroviral Therapy**

The long-term effectiveness of HAART is dependent on achieving a maximum and durable suppression of viral replication.

It is important to use a specific method for measuring adherence to HAART in clinical practice (**A-III**). Clinicians should avoid making assumptions about patients' adherence, because these assumptions are usually incorrect. Ideally, the adherence measurement strategy should be easily incorporated into clinical care, be inexpensive, and be helpful in assessing both baseline adherence and the effectiveness of adherence interventions.

It is important to assess patient readiness and commitment to therapy before initiating HAART. If readiness appears low, HAART should be deferred while efforts such as education and time to address concerns or barriers are undertaken to improve the patient's readiness. When therapy is begun, a regimen should be carefully chosen that has the highest likelihood of patient adherence on the basis of regimen characteristics and patient preferences. At the time that HAART is started, adherence interventions chosen on the basis of the patient's specific needs and situation should be provided.

### **Patient-Focused Adherence Strategies**

The following strategies may be helpful in modifying these patient factors that influence adherence:

- Screen all patients for depression before initiation of HAART; if depression is found, treat and stabilize depression before initiating HAART.
- Screen patients for substance abuse and alcohol abuse, and encourage treatment. If a patient is unwilling to discontinue substance abuse but is committed to beginning HAART, use a variety of strategies to enhance his or her ability to successfully adhere to treatment. Consider placing the patient in a directly observed therapy program, if available, or in a setting in which medications will be directly administered, such as a halfway house.
- Do all that you can to assist in stabilizing the patient's living situation and social support system. Begin by establishing a clear understanding of his or her housing arrangement, the stability of that situation, and the patient's significant others. Collaborate with a case manager or social worker to effectively address these issues.
- Assess the patient's beliefs and perceptions about HAART. Consider the use of a support group, peer educator, or "treatment buddy" if the patient has negative perceptions of HAART or does not believe that the medications will work.
- When providing educational materials for patients, be mindful of their reading skills and primary language. Whenever possible, provide dosing schedules that maximize the use of pictures, especially photographs of the medications. Assess the patients' primary-language reading skills before giving materials in that language as well.
- Offer structured individualized or group educational sessions about antiretrovirals, how they work, the importance of adherence, and strategies for adherence. These have been found to be effective in a number of studies and settings and can be administered by a nurse, health educator, peer

- counselor, pharmacist, or other staff members, either on a one-on-one basis or in a group setting.
- With the patient's help, identify a family member, friend, or partner who will assist with and help take responsibility for the patient's medication taking and adherence. This will serve to enhance social support while enhancing adherence.

Focus on potentially modifiable patient factors in an effort to enhance the patients' likelihood of adherence. Never use personal characteristics that patients are unable to change as a reason for withholding HAART. Instead, use any such factors that cause concern as a reason to provide even more intensive adherence-related supports.

### **Regimen-Focused Adherence Strategies**

The following regimen focused adherence strategies are recommended:

- Prescribe simpler HAART regimens. Focus on constructing regimens that involve fewer pills and fewer doses and that minimize food-dosing restrictions.
- Individualize HAART regimens; work with each patient to choose a regimen that is tailored to his or her lifestyle and schedule. Avoid adopting a "one-regimen-fits-all" philosophy. Get the patient involved in choosing and individualizing the regimen.
- Choose regimens with fewer side effects. Whenever possible, avoid prescribing medications known to frequently cause very unpleasant side effects.
- Proactively manage side effects. Let patients know what side effects may be experienced and how each side effect will be managed if it occurs.

### **Provider-Focused Adherence Strategies**

The following provider and clinical care site focused adherence strategies are recommended:

- Develop a set of adherence-focused activities that are provided for each patient, including an assessment of readiness for HAART, education regarding importance of adherence and consequences of nonadherence, an individualized dosing-instruction sheet with photographs of medications, structured follow-up measurements of adherence, and problem-solving for adherence-related difficulties that are identified.
- Give patients the time and opportunity to develop a warm, caring patient-provider relationship with you, even if they are not yet receiving HAART or do not feel ready to begin receiving HAART.
- Try to make your clinical site as user-friendly as possible. Make it easy for patients to call and obtain answers to questions and to come in at short notice if problems develop.
- Utilize a multidisciplinary care team, if possible, so that other providers, such as nurses, case managers, pharmacists, and peer counselors, will be available to coordinate some of the adherence-related activities.
- Schedule intensive and frequent visits during the month after initiation of HAART. Focus on identifying and solving adherence problems and difficulties

with medication tolerance. These visits can also be used to obtain early measures of adherence and to reinforce the correct dosing schedule.

### **Definitions**

#### **Strength of Recommendation**

- A. Good evidence to support a recommendation for use; should always be offered
- B. Moderate evidence to support a recommendation for use; should generally be offered
- C. Poor evidence to support a recommendation; optional
- D. Moderate evidence to support a recommendation against use; should generally not be offered
- E. Good evidence to support a recommendation against use; should never be offered

#### **Quality of Evidence**

- I. Evidence from  $\geq 1$  properly randomized, controlled trial
- II. Evidence from  $\geq 1$  well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from  $>1$  center); from multiple time-series; or from dramatic results from uncontrolled experiments
- III. Evidence from opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committee

#### **CLINICAL ALGORITHM(S)**

None provided

### **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is identified and graded for selected recommendation (see Major Recommendations). Guidelines endorsed by the United States Public Health Service, the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC), Infectious Diseases Society of America (IDSA), or other accredited programs provide supplemental information.

### **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

#### **POTENTIAL BENEFITS**

- Decreased incidence of opportunistic infection in patients with HIV
- Decreased morbidity and mortality related to HIV
- Increased quality and duration of life

#### **POTENTIAL HARMS**

- Risk of false-positive and false-negative test results for human immunodeficiency virus (HIV) infection
- Metabolic complications of antiretroviral therapy (see "Major Recommendations")

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

These guidelines discuss the following topics: (1) transmission of HIV infection; (2) HIV diagnosis; (3) risk screening; (4) management, with special sections concerning women and children; and (5) adherence. It is not the intent of the guideline authors to duplicate the extensive guidelines endorsed by the United States Public Health Service, the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC), IDSA, or other accredited programs. The guideline authors have referred to these guidelines where applicable, so that this document may also serve as a "guide to the guidelines."

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness  
Staying Healthy

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Aberg JA, Gallant JE, Anderson J, Oleske JM, Libman H, Currier JS, Stone VE, Kaplan JE. Primary care guidelines for the management of persons infected with human immunodeficiency virus: recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis 2004 Sep 1;39(5):609-29. [76 references] [PubMed](#)

## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

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## **GUIDELINE DEVELOPER(S)**

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## **GUIDELINE COMMITTEE**

Not stated

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

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*Conflicts of interest.* All authors: No conflict.

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [Infectious Diseases Society \(IDSA\) Web site](#).



Print copies: Available from Infectious Diseases Society of America, 1300 Wilson Boulevard, Suite 300, Arlington, VA 22209.

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

- Kish MA. Guide to development of practice guidelines. Clin Infect Dis 2001 Mar 15;32(6):851-4.

Electronic copies: Available from the [Clinical Infectious Diseases Journal Web site](#).

Print copies: Available from Infectious Diseases Society of America, 1300 Wilson Boulevard, Suite 300, Arlington, VA 22209.

A PDA version of the original guideline document is available from [www.idsaguidelinesforhandhelds.org](http://www.idsaguidelinesforhandhelds.org).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This summary was completed by ECRI on November 5, 2004. This summary was updated by ECRI on March 3, 2006 following the FDA advisory on varicella zoster immune globulin (VZIG).

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